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Docket No. ALL-T101D1
Serial No. 10/643,298Remarks

Claims 1-15 were pending in the subject patent application. By this amendment, claims 1-3, 5, 6, 8, 9, 11-13 and 15 have been amended and claims 4 and 10 have been cancelled. Support for the amendment can be found throughout the specification. No new matter has been added by this Amendment. Accordingly, claims 1-3, 5-9 and 11-15 are before the Examiner for consideration.

The amendments (and claim cancellations) set forth herein should not be taken to indicate the applicant's agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

As an initial matter, the Declaration and Power of Attorney form has been objected to for not adequately identifying the specification to which the oath/declaration is directed. By this amendment, a new Declaration and Power of Attorney form is submitted to address this objection. Reconsideration and withdrawal of this objection is respectfully requested.

Claims 5, 8, 12, and 15 have been objected to because of informalities. The applicant would like to thank the Examiner for her careful reading of the specification and claims as well as her helpful suggestions regarding the informalities identified. The applicant has amended claims 5, 8, 12, and 15 to address the noted informalities. Accordingly, the applicant respectfully requests reconsideration and withdrawal of this objection.

The specification was also objected to because of informalities. Again, the applicant would like to thank the Examiner for her careful review of the application and suggestions regarding the identified informalities. By this amendment, the applicant has amended the specification to address the noted informalities. Reconsideration and withdrawal of this objection is respectfully requested.

Claims 2, 8 and 14 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. It appears that this rejection was intended to be applied to claim 15 rather than to claim 14. Accordingly, the applicant has amended claims 2, 8 and 15 to expedite prosecution and to address the issue raised by the Examiner. The applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. §112, second paragraph.

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Claims 4 and 10 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The applicant has cancelled claims 4 and 10 thereby rendering moot this ground for rejection.

Claim 1 has been rejected under 35 U.S.C. §102(b) as being anticipated by Winitz (U.S. Patent No. 3,697,287). The applicant respectfully traverses this ground of rejection because the cited reference does not disclose the applicant's unique composition.

It is basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra*; *Kalman [v. Kimberly-Clarke]*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

Furthermore, the applicant respectfully points out that for a claim to be anticipated under the principles of inherency, the subject of a single prior art reference must necessarily function in accordance with the limitations of the process or method claimed. *In re King*, 801 F.2d 1324, 1326, 231 USPQ 136, 138 (Fed. Cir. 1986). Further,

the doctrine of inherency is available only when the prior inherent event can be established as a certainly. That an event may result from a given set of circumstances is not sufficient to establish anticipation. . . . A prior inherent event cannot be established based on speculation, or where a doubt exists (emphasis added). *Ethyl Molded Product Co. v. Betts Package Inc.*, 9 USPQ 2d 1001, 1032-33 (E.D. KY 1988).

Please note that unlike the Winitz composition, the muscle-stimulating amino acid component of the composition of the current invention is only arginine with optional leucine, isoleucine, and valine. By contrast, the Winitz reference discloses compositions with a plethora of amino acids. Furthermore, it is by no means a certainty that the Winitz composition has

sufficient amounts of any amino acid(s) to stimulate muscle growth. Thus, Winitz does not disclose, within its four corners, all of the elements of the claimed invention. Accordingly, the applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b).

Claims 1-5 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Winitz (U.S. Patent No. 3,697,287) as applied to claim 1, and further in view of Durst (U.S. Patent No. 3,434,843) and Millman (U.S. Patent No. 4,871,550). The applicant respectfully traverses this ground for rejection because the cited references, alone or in combination, do not disclose or suggest that applicant's unique composition which has only specific amino acid constituents.

The shortcomings of the Winitz reference with respect to the current invention have been discussed above. The secondary Durst and Millman references do not cure or even address these deficiencies.

It has been well established in the patent law that the mere fact that the purported prior art could have been modified or applied in some manner to yield applicant's invention does not make the modification or application obvious unless the prior art suggested the desirability of the modification. *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984). However, as expressed by the CAFC, to support a §103 rejection, "[b]oth the suggestion and the expectation of success must be founded in the prior art ..." *In re Dow Chemical Co.* 5 USPQ 2d 1529, 1531 (Fed. Cir. 1988). One finds neither the suggestion nor the expectation of success in the cited references, either separately or combined. An assertion of obviousness without the required suggestion or expectation of success in the prior art is tantamount to using applicant's disclosure to reconstruct the prior art to arrive at the subject invention. Hindsight reconstruction of the prior art cannot support a §103 rejection, as was specifically recognized by the CCPA in *In re Spinnoble*, 56CCPA 823, 160 USPQ 237, 243 (1969).

In the current case, the cited references are not even addressing the problem addressed by the current invention -- stimulating muscle growth in a palatable, efficient and metabolically favorable way. Thus, there would be no motivation to modify the Winitz composition to arrive

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at the composition of the current invention. Without such a motivation, and an expectation of success, the claimed invention cannot be said to be obvious.

The Court of Customs and Patent Appeals was faced with an analogous situation in *In re Hayashibara and Sugimoto*, 188 USPQ 4 (CCPA 1975). The PTO Board of Appeals had affirmed a §103 rejection, and the CCPA reversed, stating:

Turning to the . . . rejection . . . for obviousness under 103, we agree with appellants that there is nothing in the reference which would lead those of ordinary skill in the art to employ [the substance] as appellants do in the product of claim 11. The reference does not teach [the substance] as possessing any of the characteristics or functions upon which appellants' claimed invention depends (emphasis added).

The applicant respectfully submits that the cited references, even when combined, do not disclose or suggest, or provide any motivation to arrive at, the applicant's unique muscle stimulating composition having only specifically selected and identified amino acids. Accordingly, the applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §103 based on Winitz in combination with Durst and Millman.

Claims 10-21 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Rudman *et al.* ("Growth Hormone Treatment of Frailty In Men Over 60" *New England Journal of Medicine*, 1990), Dudrick *et al.* (U.S. Patent No. 5,026,721, 1991), and Boynton *et al.* (U.S. Patent No. 5,087,624 (Issued 1992; priority to 1987)). Initially, the applicant respectfully notes that it appears that this rejection was intended to be applied to claims 6-15. Also, please note that the "Rudman" reference is actually authored by Pearson and Shaw, with a quote to Rudman in the first paragraph. In any event, the applicant respectfully traverses this ground for rejection because the cited references, alone or in combination, do not disclose or suggest the use of the applicant's specific composition to stimulate muscle growth or enhance immunity.

Please note that the applicant's claims have been amended herein to lend greater clarity to the claimed subject matter.

As noted in the introductory part of the specification, the problem of maintaining muscle mass while minimizing the accumulation of fat has long been an issue of concern, especially with athletes. While exercise is one of the main mechanisms for achieving that goal, food and/or

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vitamin supplements as well as pituitary growth hormone are necessary for muscle growth. Growth hormone produces an anabolic effect which includes the process of converting amino acids to protein. The cost of human growth hormone is very high, making it unattractive for use commercially. The use of steroids to improve performance and increase muscle mass is fraught with disadvantages. In particular, anabolic steroids have undesirable side-effects which are linked to a variety of serious health problems, including cardiovascular disease and liver cancer.

In light of the above background, the present inventor has sought to provide a composition useful for providing a safe and effective method of stimulating muscle growth which will take the place of steroids, thereby producing the desired results with minimum side-effects. Surprisingly, the current inventor has found that a composition with only a very limited number of amino acids, including L-arginine is highly effective in promoting muscle growth. The particular formulation is quite unexpected because, at the time of the invention, those skilled in the art believed that arginine should be combined with lysine.

Specifically, a noted disadvantage associated with L-arginine is that when administered on its own, arginine tends to promote herpes 1 and 2, which gives rise, amongst other adverse effects, to mouth sores and genital discomfort. It is known that L-lysine inhibits the growth of such viruses, and so lysine is conventionally administered with arginine to minimize the onset of herpes.

It has been discovered, surprisingly, according to the present invention that it is possible to administer L-arginine in the present composition without lysine. This is contrary to the conventional wisdom that existed at the time of the present invention, which suggested administration of lysine with arginine help mitigate herpes problems. The claims now presented in this application exclude the presence of lysine by the use of the expression "consisting essentially of" to define the amino acid component of the composition.

The references to Dudrick *et al.* and Boynton *et al.* do not cure the deficiencies of the primary Pearson *et al.* (Rudman) reference. For example, Dudrick *et al.* provide an amino acid supplement comprising, as "primary" amino acids, arginine, leucine, valine and lysine (column 2, lines 48-50). Thus, if anything, Dudrick *et al.* teach away from the current invention. Boynton does not address this issue at all.

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In light of the above teachings, it is clear that a person of ordinary skill, given the combination of Rudman *et al.*, Dudrick *et al.* and Boynton, would have been motivated at the date of the present invention to include L-lysine with L-arginine. In the present invention, lysine is specifically excluded.

The applicant further respectfully submits that there is no disclosure in Pearson *et al.* suggesting the combined use of leucine, isoleucine and valine.

A further distinction between the subject invention and the teachings of Pearson *et al.* is that the high doses of choline used by Pearson *et al.* causes users to have a very strong and offensive smell. Pearson *et al.* suggests that an arginine supplement must be accompanied by high doses of choline. For example, at page 6, Pearson *et al.* state that "we recommend that, if you are taking arginine supplements, you also take one to three grams of choline ..." However, in contrast, the current applicant wishes to emphasize that the subject composition contains an especially small dose of choline, which, advantageously, eliminates the occurrence of body odor.

"Obviousness cannot be predicted on what is unknown." *In Re Spormann*, 150 U.S.P.Q. 449, 452 (C.C.P.A. 1966). In the current case it was not known, or even suspected, that the presently claimed compositions and/or methods could be used to safely and effectively stimulate muscle growth and enhance the immune system.

The applicant respectfully submits that there is nothing in the cited art which would motivate the skilled artisan to produce the specific, unique and advantageous composition as currently claimed. Accordingly, in view of the foregoing remarks, reconsideration and withdrawal of the rejection under 35 U.S.C. 103 based on the cited references is respectfully requested.

Claims 1-15 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,608,109. In order to expedite prosecution, the applicant is attaching herewith a Terminal Disclaimer with regard to U.S. Patent No. 6,608,109. Please note that the submission of this Terminal Disclaimer should not be taken to imply that the applicant agrees with, or acquiescence to, this double patenting rejection.

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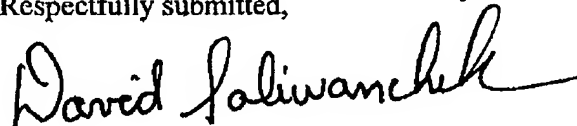
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In view of the foregoing remarks and the amendments above, the applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR 1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

The applicant also invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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Attachment: Terminal Disclaimer (2 pages)
Executed Declaration and Power of Attorney form

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